REMARKS

Claims 1-11, 21-30, 36-45, 51-62 and 64 are pending. The Applicant respectfully requests the Examiner to reconsider the rejections in view of amendments to the claims now presented and the following remarks.

In view of the amendments to claims 23-24, and 38-39 presented herewith, all claims now pending stand on their own in view of the specification. The Applicant accordingly respectfully requests the Examiner to withdraw all objections to the claims since no claim now pending literally refers to the figures.

Rejection under 35 USC §112, paragraph 2

The Applicant now presents amended claim 6 which now merely refers to "polymer" which indeed has antecedent basis from claim 1. Accordingly, the Applicant respectfully requests the Examiner to withdraw the rejection.

Rejection under 35 USC §103

The subject matter of all pending claims is alleged by the Examiner to be obvious under 35 USC §103(a) over U.S. Patent 5,922,342 (Shah, *et al.*,'342) in view of Published U.S. Application 2001/0038853 (Kendrup, *et al.*,'853).

The Applicant's invention is fundamentally a controlled release drug delivery device wherein a pharmaceutical agent is released according to a predetermined profile due to the surface area of the exposed faces of the core. Particularly, a core is surrounded by an insoluble polymer coating comprising water-soluble pore-forming material(s) that leach out of the coat and that introduce mechanical instability and allow the coat to disintegrate *after release of the active compound is complete.*[1] The pores, however, in contrast to the prior art, do not alter the release rate of the active ingredient. Specification, page 16, lines 8-9. In other words, in contrast to prior art embodiments which employ pore-forming material(s) to effect release, the instant

[1] Specification, page 10, line 30 - page 11, line 3.

invention effects drug release at the exposed faces not through the coat.[2] In sharp contrast, the pores that form in the coat of the instant invention do not alter the drug release rate. Particularly, embodiments of the present invention are designed to form pores *after the drug release* period is substantially complete. Specification, page 13, lines 23-25. The purpose of the coat is to prevent the coated surface of the core from imbibing dissolving fluids. The drug in the core dissolves from the uncoated faces when exposed to the dissolving fluid. The coat remains intact throughout the delivery period but disintegrates prior to evacuation from the colon. Specification, page 17, lines 21-22.

Shah, *et al.*,'342

The '342 disclosure describes a compressed core and a seal coating surrounding the core except on planar surfaces (i.e. on all lateral surfaces). The seal coating comprises a film coating of a *necessarily* impermeable material. Shah, *et al.*, Col.2, line 64 - Col.3, line 3. Therapeutic agent is released from the two planar surfaces. The seal coating serves to protect the lateral surfaces of the core. Moreover, the residual coat remains intact after all of the drug is released. An impermeable seal coating is expressly *required* on all surfaces except the release faces. Col.3, lines 28-29.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.01.

[2] In contrast, prior art pore-forming materials dissolve or leach out of the coating which creates paths or channels allowing ingress of the surrounding fluids which dissolve the active compound and produce saturated solutions of the active compound in the core which subsequently egress through the same channels. *See*, e.g., Specification, page 8, lines 4-8.

Kendrup, *et al.*,'853 (pore-forming function)[3]

The object of the Kendrup, *et al.*,'853 device is to have drug released at a predetermined rate *through the pores*. The size of the pores determines the rate of release of the drug from the tablet. It is imperative that pores are formed within minutes of contact of the core with the dissolving medium and channels for transport of the dissolved drug are created for the transportation of the drug. The coat remains stable and residually intact after the release of the drug.

> "When the tablet is then contacted with the GI juices of a patient, these particles dissolve and create a network of canals or pores of a predetermined size in the polymer coating and *the drug is released through these pores or canals*. Due to this network the coating will get good mechanical stability and the polymer film will be left intact after the release of the drug." Kendrup, *et al.*,'853, para.12 (emphasis added).

In sharp contrast to the disclosure of Kendrup *et al.*, the nature of pore formation in claimed embodiments of the present invention is very different. Particularly, embodiments of the present invention are constructed to form pores *after* substantially all the active ingredient has been released. The pore-forming elements do not influence the release of the active ingredient. Moreover, the purpose of pore formation, *per se*, is to provide properly timed disintegration of the coat, i.e., after the release of the active ingredient, but before evacuation from the colon. **The claims now presented require this distinction.**

The Applicant respectfully refers the Examiner to the Applicant's amendments presented herewith, i.e., to independent claims 1, 21-22, 36-37, 51-52 and 63. Particularly, independent claims 1, 21-22, 36-37 and 51 now require that the pore-forming elements do not alter a release rate of the active ingredient. As mentioned *supra*, this limitation is in sharp contrast to the disclosure of Kendrup, *et al.*, wherein the pore-forming elements are employed in fact to control the release of the active ingredient.[4]

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[3] The '853 disclosure describes a controlled-release pharmaceutical device having a particle-containing coating derived from a water insoluble polymer and a water soluble pore-forming agent. The coat creates, when subject to GI fluid, canals or a network of pores.

[4] Independent claims 52 and 63 now require that the coating disintegrate over a substantially longer period of time than is required for the release of the active ingredient but prior to evacuation from the colon.

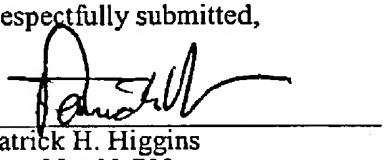
A combination of these references, accordingly, does not produce the Applicant's invention.[5] The Applicant accordingly respectfully requests the Examiner to withdraw the rejection.

* * *

For all the foregoing reasons, the Applicant submits that claims 1-11, 21-30, 36-45, 51-62 and 64 are in condition for allowance. Early action toward this end is courteously solicited. *The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution*.

The Commissioner is authorized to charge any deficiency or credit any overpayment in connection herewith to Deposit Account No.13-2165.

Respectfully submitted,



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[5] The prior art references when combined must teach or suggest all the claim limitations. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Deficiencies of the cited references cannot be remedied by general conclusions about what is 'basic knowledge' or 'common sense.' *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.01.

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